APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,270	09/29/2003	Christopher S. de Voir	117163.00092	3098

21324   7590   11/05/2008
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EXAMINER
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ART UNIT	PAPER NUMBER
2129	

NOTIFICATION DATE	DELIVERY MODE
11/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)
	10/674,270	DE VOIR ET AL.
Office Action Summary	Examiner	Art Unit	
	NATHAN H. BROWN JR	2129	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>(3)</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>27 August 2008</u>.

2a) ☐ This action is **FINAL.**   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-6 and 8-17</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-6 and 8-17</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
         application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

Examiner's Detailed Office Action

1. This Office Action is responsive to the communication for

application 10/674,270, filed August 27, 2008.

2. Claims 1-6 and 8-17 are pending. Claims 1-6 and 8-17 are

previously presented.

3. After the previous office action, claims 1-6 and 8-17 stood

rejected.

Objections to the Claims

4. Claim 1 is objected to because of the following

informalities: "a transformation unit which is designed to

carry out transformation of the physiological signal in such a

way that as the output signal it outputs a number of values

representing the physiological signal and based on the

transformation" should be --a transformation unit which is

designed to carry out transformation of the physiological signal

in such a way that it outputs a number of values representing

the physiological signal and based on the transformation--.

Appropriate correction is required.

Claim Rejections – 35 USC § 112, 1st

5. The following is a quotation of the first paragraph of 35
U.S.C. 112:

> The specification shall contain a written description of the invention,
> and of the manner and process of making and using it, in such full,
> clear, concise, and exact terms as to enable any person skilled in the
> art to which it pertains, or with which it is most nearly connected, to
> make and use the same and shall set forth the best mode contemplated by
> the inventor of carrying out his invention.

6. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 112, first

paragraph, as failing to comply with the written description

requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the

claimed invention. Independent claim 1 recites an "apparatus

for the classification of physiological events" having "a

transformation unit which is designed to carry out

transformation of the physiological signal *in such a way that it*

outputs a number of values representing the physiological signal

and based on the transformation" [emphasis added]; however no

processor, memory, or machine readable medium is described in

the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed

transformation unit designed to carry out transformation of a

physiological signal.

7. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 112, first

paragraph, as failing to comply with the enablement requirement.

The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. Independent claim 1

recites an "apparatus for the classification of physiological

events" having "a transformation unit which is designed to carry

out transformation of the physiological signal *in such a way

that it outputs* a number of values representing the

physiological signal and based on the transformation" [emphasis

added]; however no processor, memory, or machine readable medium

is described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the transformation

unit designed to carry out transformation of a physiological

signal.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine,
> manufacture, or composition of matter, or any new and useful
> improvement thereof, may obtain a patent therefor, subject to the
> conditions and requirements of this title.

9. Claims 1-6 and 8-17 are rejected under 35 U.S.C. 101 because

the claimed invention is directed to non-statutory subject

matter: non-functional descriptive material or software per se.

Independent claim 1 recites an "apparatus for the classification

of physiological events" having "a transformation unit which is

designed to carry out transformation of the physiological signal

in such a way that it outputs a number of values representing

the physiological signal and based on the transformation"

[emphasis added]; however the transformation unit is not defined

in terms of a functional arrangement of a processor, memory, or

machine readable medium. Therefore, the "transformation unit"

(unlike the "signal preparation unit" which *is* defined in terms

of function hardware, i.e., an: anti-aliasing filter, broadband

analog-digital converter or A/D-converter) is considered to be a

non-functional description or software per se. Thus,

independent claim 1 is considered to be non-statutory under 35

U.S.C. 101. Claims 2-6 and 8-17 provide further technical

limitation to claim 1, but do not cure the deficiency of claim

1. Therefore, claims 1-6 and 8-17 are considered to be non-

statutory under 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms

the basis for all obviousness rejections set forth in this

Office action:

   (a) A patent may not be obtained though the invention is not identically
   disclosed or described as set forth in section 102 of this title, if the
   differences between the subject matter sought to be patented and the prior
   art are such that the subject matter as a whole would have been obvious at
   the time the invention was made to a person having ordinary skill in the
   art to which said subject matter pertains. Patentability shall not be
   negatived by the manner in which the invention was made.

11. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being

unpatentable over **Esteller** et al. (*Esteller*) (USPN 6,594,524)

in view of **Gillberg** (USPN 6,393,316).

Regarding claim 1. (Previously presented) *Esteller teaches an*

apparatus for the classification of physiological events (*see*

Abstract, *Examiner interprets "forecasting" to be a*

classification task where the input is a description of some

earlier event and the output is the identification of some event

that follows (or results from) the earlier event.), comprising:

a signal input for the input of a physiological

signal representing or constituting a physiological event

(*see* col. 9, lines 34-36);

a classification unit (*see* Fig. 3, item 200

"Intelligent Data Processing Unit") for classifying the

physiological signal on the basis of its signal shape (*see* col.

18, lines 44-50), the classification unit comprising:

a transformation unit which is designed to

carry out transformation of the physiological signal in

such a way that as the output signal it outputs a number of

values representing the physiological signal and based on the

transformation (*see* Fig. 4, preprocessing 210 and feature

extraction; col. 9, lines 20-25; col. 20, lines 26-36); and

a probabilistic neural network which is connected

to the transformation unit to receive the values (see

Fig. 32, col. 36, lines 43-50) and which contains a number

of event classes which represent physiological events

(see Fig. 32, col. 36, lines 30-33) and which in turn are

each represented by a set of comparative values, which

probabilistic neural network is adapted on the basis of the

comparison of the values with the comparative values to effect

an association of the physiological signal represented by the

values with one of the event classes (*see* col. 36, lines 55-56

and col. 37, lines 27-36, *Examiner interprets "weights used at*

the hidden layer of the PNN" to be comparative values, which the

probabilistic neural network is adapted on.).

Esteller does not teach an adjusting unit for centering the

physiological signal in a time window of predetermined window

width and for outputting the centered physiological signal to

the transformation unit, the adjusting unit connected upstream

of the transformation unit.

However, *Gillberg* does teach an adjusting unit for centering the

physiological signal in a time window of predetermined window

width and for outputting the centered physiological signal to

the transformation unit, the adjusting unit connected upstream

of the transformation unit (*see* Figs. 2 and 6 and col. 16, lines

15-24, "The 64 sample segment of data (254 milliseconds) was

extracted from a continuous multi-channel recording using the

technique of centering a morphology window around the bipolar

sensed ventricular depolarization...", *Examiner interprets the*

"Microprocessor 524" to be an adjusting unit connected upstream

of the transformation unit "A/D 530 and RAM 526" (see Fig. 2).).

It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller* with *Gillberg* to monitor heart rhythms.

Regarding claim 2. *Esteller* teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (*see* col. 28, lines 21-44).

Regarding claim 3. *Esteller* teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (*see* Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

Claim Rejections - 35 USC § 103

12. Claims 4-6, 8, 9, and 11-17 are rejected under 35 U.S.C.

103(a) as being unpatentable over *Esteller* in view of *Gillberg*

and further in view of *Echauz* et al. (*Echauz*) (USPN 6,678,548).

Regarding claims 4, 11, and 12.   *Esteller* teaches the apparatus

of claim 3, wherein the probabilistic neural network further

comprises: at least one ascertaining unit for determining

association probabilities of the physiological signal with the

event classes on the basis of the comparison of the values with

the comparative values of the respective event class and for

outputting the ascertained association probabilities (*see* Fig.

32, col. 37, lines 11-20). *Esteller* does not expressly teach

selection unit which is connected to the ascertaining unit for

receiving the association probabilities and which is adapted to

extract the highest association probability from the association

probabilities and to associate the physiological signal with the

event class having the highest association probability (it is

disclosed in Fig. 32 as competitive layer, but without. a

detailed explanation). However, *Echauz* teaches selection unit

which is connected to the ascertaining unit for receiving the

association probabilities and which is adapted to extract the

highest association probability from the association

probabilities and to associate the physiological signal with the

event class having the highest association probability (*see* col.

26, lines 36-39 mention competitive layer as a maximum selector;

see also col. 18, lines 53-66). It would have been obvious to a

person of ordinary skill in the art at the time of the invention

to include the details on implementation of a probabilistic

neural network from *Echauz* and combine it with the probabilistic

neural network of *Esteller* and *Gillberg* in order to find the

details of how the probability of having a seizure is estimated.

Regarding claim 5. *Esteller* teaches the apparatus of claim 4,

wherein: two or more sets of comparative values representing the

same event class are present for at least one event class (*see*

col. 13, lines 39-44).

Regarding claim 6. *Esteller* teaches the apparatus of. claim 5,

wherein: the ascertaining unit is adapted to determine a

plurality of association probabilities for each event class

which has two or more sets of comparative values representing

the same event class (*see* Fig. 32, T values; col. 37, lines 22-

26), and the selection unit is so designed that, for those event

classes which have two or more sets of comparative values

representing the same event class, it forms average values of

the corresponding association probabilities and , upon

extraction of the highest association probability uses the

average values instead of the individual values (*see* Fig. 32,

averaging operation on Ts is shown in circles in the output

layer; col. 37, lines 12-20, averaged T1 and T2 form

probabilities PI and P2 correspondingly).

Regarding claim 8.   *Esteller* teaches the apparatus of claim 6.

Esteller does not teach the apparatus of claim 6, wherein: in

those event classes which include two or more sets of

comparative values representing the same event class, the sets

of comparative values correspond to different offsets in the

centering of the centered physiological signal. *Gillberg* does

teach that, in those event classes which include two or more

sets of comparative values representing the same event class

(*see* col. 15, lines 28-57, *Examiner interprets '"unknown" EGM*

waveforms' to be an event class which includes two or more sets

of comparative values (i.e., "EGM waveforms from the ongoing

rhythm are obtained at 306") representing the same event

class.), the sets of comparative values correspond to different

offsets in the centering of the centered physiological signal

(*see* Fig. 6 and col. 3, line 15 to col. 16, line 14, *Examiner*

interprets the wavelets derived from the DWT that describe "the

signal in terms of a basis that represents the features of the

signal at different time-scales (i.e. resolutions)" to be sets

of comparative values correspond to different offsets in the

centering of the centered physiological signal.). It would have

been obvious at the time the invention was made to persons

having ordinary skill in the art to combine *Esteller* with

Gillberg to monitor heart rhythms.

Regarding claim 9. *Esteller* teaches an implantable medical

device characterized in that it is provided with an apparatus

for the classification of physiological events as set forth in

claim 8 (*see* Abstract).

Regarding claim 10. *Esteller* teaches the implantable medical

device of claim 9 (*see* Abstract). *Esteller* does not teach that

the implantable medical device is in the form of a cardiac

pacemaker or defibrillator. *Gillberg does* teach that the

implantable medical device is in the form of a cardiac pacemaker

or defibrillator (*see* col. 1, lines 10-13). It would have been

obvious at the time the invention was made to persons having

ordinary skill in the art to combine *Esteller* with *Gillberg* to

monitor heart rhythms.

Regarding claim 13. *Esteller* teaches the apparatus of claim 1,

wherein: two or more sets of comparative values representing the

same event class are present for at least one event class (*see*

col. 13, lines 39-44).

Regarding claim 14. *Esteller* teaches the apparatus of claim 11,

wherein: two or more sets of comparative values representing the

same event class are present for at least one event class (*see*

col. 13, lines 32-36, *Examiner interprets "electrical, magnetic,*

chemical, sensorial or cognitive stimulation variables" to be

comparative values representing the same event class are present

for at least one event class.).

Regarding claim 15. *Esteller* teaches the apparatus of claim 12,

wherein: two or more sets of comparative values representing the

same event class are present for at least one event class (*see*

above).

Regarding claim 16. *Esteller* teaches the apparatus of claim 14,

wherein: the ascertaining unit is adapted to determine a

plurality of association probabilities for each event class

which has two or more sets of comparative values representing

the same event class (*see* Fig. 32, col. 37, lines 21-26,

Examiner interprets the entries of Matrix T to determine a

plurality of association probabilities for each event class.),

and the selection unit is so designed that, for those event

classes which have two or more sets of comparative values

representing the same event class, it forms average values of

the corresponding association probabilities (*see* Fig. 32,

Examiner interprets the output units P_1 and P_2 to form the

average of T_{1j} and T_{2j}, respectively, where each T_{ij} is "the

probability that the input signals belong to the pre-

seizure/seizure class".) and upon extraction of the highest

association probability uses the average values instead of the

individual values (*see* Fig. 32, *Examiner interprets the units of*

the "Competitive Layer" to extract the highest association

probability by picking one of P_1 or P_2 which use the average of

T_{1j} and T_{2j}, respectively.).

Regarding claim 17. *Esteller* teaches the apparatus of claim 15,

wherein: the ascertaining unit is adapted to determine a

plurality of association probabilities for each event class

which has two or more sets of comparative values representing

the same event class (*see* Fig. 32, col. 37, lines 22-26,

Examiner interprets the entries of Matrix T to comprise two or

more sets of comparative values representing the same event

class (e.g., T11 and T21 emanate from the same hidden unit,

which represents a class of pre-seizure data).), and the

selection unit is so designed that, for those event classes

which have two or more sets of comparative values representing

the same event class, it forms average, values of the

corresponding association probabilities and upon extraction of

the highest association probability uses the average values

instead of the individual values (*see* Fig. 32, *Examiner*

interprets the units of the "Competitive Layer" to extract the

highest association probability by picking one of P_1 or P_2 which

use the average of T_{1j} and T_{2j}, respectively.).

New grounds of rejection have been added.

Response to Arguments

13. Applicant's arguments filed August 27, 2008 have been fully

considered.

Rejection of Claims 1-6 and 8-17 Under 35 U.S.C. §112, first

paragraph

Applicant(s) argue(s):

        The idea that the physiological signal of the claimed
    invention of claim 1 is automatically time-centered in a
    time window is well supported by the specification. The
    following refers to the substitute specification of the
    present application:
        The entire specification is written in the context of
    implantable medical devices such as cardiac pacemakers and
    defibrillators. All internal functions of such devices are
    inherently automatic.

Examiner responds:

    Examiner finds applicants' arguments persuasive; however,

    the arguments are moot, based on new grounds of rejection.

    Applicants' arguments in this area also raise new grounds

    of rejection under U.S.C 112 and U.S.C 101.

        Rejection of Claims 1-3 Under 35 U.S.C. §103(a)

Applicant(s) argue(s):

        In the current Office action, claims 1-3 are rejected
    under 35 U.S.C. 103(a) as being unpatentable over Esteller
    (US 6,594,524), hereinafter Esteller, in view of Voelz (US
    4,779,100), hereinafter Voelz. The Examiner finds no
    recitation of"automatically time-centering a physiological
    signal" in Applicants' specification and thus considers the
    Applicants' argument moot.

        Applicants respectfully traverse the foregoing
    rejections in view of the above pending claims and for
    reasons set forth hereafter.

        Esteller does not teach or suggest an adjusting unit
    for automatically time-centering a physiological signal
    with respect to the time dimension in a time window of
    predetermined window width in the time dimension as does
    the claimed invention of claim 1. Furthermore, Voelz does

not teach or suggest an adjusting unit for automatically
time-centering a physiological signal with respect to the
time dimension in a time window of predetermined window
width in the time dimension as does the claimed invention
of claim 1.

Examiner responds:

Applicants' arguments are moot, based on new grounds of

rejection.

Correspondence Information

Any inquiry concerning this communication or earlier

communications from the examiner should be directed to Nathan H.

Brown, Jr. whose telephone number is 571-272- 8632. The

examiner can normally be reached on M-F 0830-1700. If attempts

to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, David Vincent can be reached on 571-272-

3080. The fax phone number for the organization where this

application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be

obtained from the Patent Application Information Retrieval

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/Nathan H. Brown, Jr./
Examiner, Art Unit 2121
November 4, 2008

/David R Vincent/

Supervisory Patent Examiner, Art Unit 2129